



Richard B. Rosenthal, Esq

December 4, 2023

VIA ELECTRONIC CASE FILING ONLY

Honorable P. Kevin Castel, U.S.D.J.
Daniel Patrick Moynihan U.S. Courthouse
500 Pearl Street
New York, New York 10007

Re: Schottenstein et al. v. FDA et al., Capla et al., and Orthogen International GmbH et als.; 1:22-cv-10883-PKC;

Plaintiffs' Response to Defendants' Letter Motion for seeking clarification (CM/ECF Document # 94).

Dear Judge Castel:

The undersigned together with Cory Hal Morris, Esq. and Jeffrey A. Donner, Esq. represent plaintiffs herein. In response to Mr. Harwood's letter motion seeking clarification (CM/ECF Document # 94), the Court should note that, on November 2, 2023 the Plaintiffs filed a Notice Of Voluntary Dismissal pursuant to Rule 41(a)(1)(A)(i) of the Federal Rules of Civil Procedure, voluntarily dismissing, without prejudice and without costs, all claims against the defendant(s) Robert M. Califf and the United States Food and Drug Administration (CM/ECF Document # 88).

On November 3, 2023 the Court granted and "So Ordered" that Plaintiffs' claims against only the Nominal Defendants in this action, the United States Food and Drug Administration, and, Robert M. Califf, M.D., Acting Commissioner of the United States Food and Drug Administration in his official capacity only, are hereby dismissed without prejudice, pursuant to Fed. R. Civ. P. 41(a)(1)(A)(i). All other claims against all of the remaining defendants shall continue and are not otherwise affected (CM/ECF Document # 89).

Thereafter, on November 13, 2023 Plaintiffs filed a letter motion to consolidate the two actions commenced by Defendant Orthogen regarding the same issues as are sought to be litigated herein with the instant action, and, for a Status Conference and to extend the time to amend the complaint. (CM/ECF Document # 90).

On November 13, 2023 the Court denied and Plaintiffs' motion to consolidate and granted the Plaintiff's motion to the extent of extending the Plaintiffs' time to amend the complaint until December 1, 2023 and otherwise denied the motion. The Docket text specifically stated "SO ORDERED. (Amended Pleadings due by 12/1/2023.). (Signed by Judge P. Kevin Castel on 11/13/2023)" (CM/ECF Document # 91).

545 E. Jericho Turnpike
Huntington Station, New York 11746
(PH) 631-629-8111 or 718-261-0200
(FAX) 631-961-8789 or 718-793-2791
richard@thedoglawyer.com

Schottenstein et al. v. FDA et al., Capla et al., Case No. 1:22-cv-10883-PKC

December 4, 2023

Page 2

Based upon the foregoing, Plaintiffs understood that the Court had granted leave to file their Third Amended Complaint without necessity of further leave of the Court or additional motion practice and, on Friday, December 1, 2023, filed their Third Amended Complaint (CM/ECF Document # 92). (On Monday, December 4, 2023, the Clerk of the Southern District of New York issued a Deficiency Notice regarding that filing (CM/ECF Document # 93) and on December 4, 2023 Plaintiffs refiled the document after correcting the deficiencies in their filing (CM/ECF Document # 94)).

If Plaintiffs' counsel misunderstood or misconstrued what we reasonably believed to be the intention of the Court based upon the language used in CM/ECF Document # 91, we respectfully apologize to the Court and respectfully request the Court accept the Plaintiffs' Third Amended Complaint as properly filed or instruct Plaintiffs' counsel in what manner we may remedy this error.

We thank the Court for its kind consideration and look forward to addressing the Court on these matters in person or electronically.

Respectfully submitted,

/s/ Richard Bruce Rosenthal
Richard Bruce Rosenthal, Esq.
Co-Counsel for Plaintiffs

545 E. Jericho Turnpike
Huntington Station, New York 11746
(PH) 631-629-8111 or 718-261-0200
(FAX) 631-961-8789 or 718-793-2791
richard@thedoglawyer.com